

## **REMARKS**

### **Allowable Subject Matter**

Applicants acknowledge with appreciation the allowance of claim 18.

### **Rejections Pursuant to 35 U.S.C. 112**

Claims 53-56 and 74-77 are rejected as failing to comply with the written description requirement. Specifically, the Examiner asserts that “[t]he currently claimed power density range of 1 W/cm<sup>2</sup> to about 10 W/cm<sup>2</sup> is considered new matter.” Applicants respectfully disagree for the following reasons.

To satisfy the written description requirement, an Applicant must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.” *See, Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). Literal support for the claimed invention, however, is not required to satisfy the written description requirement. *E.g., Ex parte Parks*, 30 U.S.P.Q.2D 1234, 1236 (Bd. App. 1993) (“[a]dequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention”); *MPEP* § 2163.02 (“[t]he subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement”); *MPEP* § 2173.05(i).

For example, in *Kolmes v. World Fibers Corp.*, the Court of Appeals for the Federal Circuit (CAFC) held that the disclosure of a cut-resistant yarn that included a non-metallic covering having two strands spirally wrapped in opposite directions around a core at a rate of “4-12 turns per inch, with 8 turns per inch being preferred” provided written description support for a claimed range of “a rate of 8-12 turns per inch.” 107 F.3d 1534 (Fed. Cir. 1997). In particular, CAFC held:

Element (c) [of the claim] requires that the covering be wrapped at a rate of 8-12 turns per inch. At col. 5, lines 38-40, the specification states that the coverings or wrappings are formed “at the rate of 4-12 turns per inch, with 8 turns per inch being preferred.” All the claimed limitations including the 8-12 turns per inch are thus well supported by the specification. *Id.* at 1539.

In the present case, Applicants explicitly disclose “irradiating the oral cavity ... with a radiation power in range of about  $1 \text{ mW/cm}^2$  to about  $10 \text{ W/cm}^2$ ...” See, Paragraph [0015] of published patent application. Further, Applicants disclose a power value of  $1 \text{ W/cm}^2$  by expressly disclosing a energy density of  $10 \text{ J/cm}^2$  deposited in about 10 seconds. That is, similar to *Kolmes*, Applicants disclose a range as well as a specific value within that range.

The Examiner, however, objects that Applicants have randomly chosen a power density of  $10 \text{ J/cm}^2$  from a disclosed range of a “about  $10 \text{ Joules/cm}^2$  to about  $100 \text{ Joule/cm}^2$ ” and an irradiation time of 10 seconds from a range of “about 10 seconds to about 1000 seconds” to deduce the power density of  $1 \text{ W/cm}^2$ . Applicants respond that the energy density of  $10 \text{ Joules/cm}^2$  and the irradiation time of 10 seconds are *expressly* disclosed as the end points of the ranges. In other words, to arrive at the power density of  $1 \text{ W/cm}^2$ , Applicants have not selected randomly a value within the disclosed ranges but have rather relied on values *expressly* disclosed as end points of the ranges.

Accordingly, Applicants respectfully contend that the specification provides written description support for the recited range of  $1 \text{ W/cm}^2$  to about  $10 \text{ W/cm}^2$  for the power density.

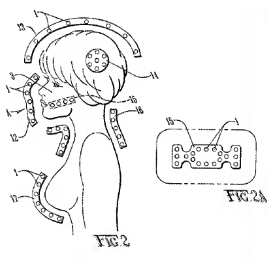
### **Rejections Pursuant to 35 U.S.C. 102**

Claims 1, 5-6, 9, 15-17, 19, 23, 24, 26, 28-30, 48-52, 57 – 73 and 78 – 104 are rejected as being anticipated by U.S. Patent No. 6,443,978 of Zharov.

Claim 1, as amended, recites a method for providing a dermatological or cosmetic treatment, which comprises: inserting at least a portion of a phototherapy applicator into an oral cavity; and irradiating a region of facial tissue below an area of facial skin by directing radiation from the phototherapy applicator to penetrate the mucosal lining of the oral cavity to the region of the facial tissue so as to deposit a dose of radiation below the area of facial skin, and having at least one wavelength component corresponding to the absorption spectrum of a light acceptor in the oral cavity or in facial tissue, wherein the region of tissue is irradiated so as to treat a dermatological or cosmetic condition in said area of the facial skin. Support for amendments to claim 1 can be found,

e.g., at paragraph [0016] of the published patent application as well as in other portions of the specification.

Zharov discloses a device for treating spatially extensive pathologies with light from a matrix of optical radiation sources “such as lasers or light diodes placed on the surface of the zone of pathology.” *See*, Abstract. For example, the device can be used to irradiate “a limb with the purpose of treating fracture, foot ulcer or skin pathologies.” *See*, col. 7, lines 41-42. Zharov’s FIGURE 2, which is reproduced below, shows one embodiment of the device in the form of a mask 12 with built-in sources of radiation, which follows the shape of the face “for cosmetological purposes to improve the blood microcirculation and metabolism of skin and to smooth wrinkles.” *See*, col. 7, lines 63 to col. 8, line 1. FIGURE 2 also shows a substrate 15 that “resembles dentures and is used to irradiate the whole mouth including the concavities near gums.” *See*, col. 8, lines 7-9.



Zharov, however, does not teach utilizing its device to irradiate a region of facial tissue below an area of facial skin so as to deposit a dose of radiation below the area of facial skin in order to treat a dermatological or cosmetic condition in that area of the facial skin. In particular, Zharov does not teach utilizing the above substrate 15 to irradiate the mouth in a way that would result in the deposition of a dose of radiation below an area of the facial skin to treat a dermatological or cosmetic condition of the facial skin. In fact, for treating such conditions, Zharov discloses the above mask 12, which is configured to irradiate the facial tissue in a conventional manner and not from inside the oral cavity.

Nor is there any reason to believe that the use of the substrate 15 of Zharov would inherently result in the treatment of the facial skin, as recited in claim 1. The Examiner, however, refers to Zharov's claim 64 as well as other portions of Zharov to assert otherwise. Specifically, the Examiner asserts:

Zharov discloses a power density of  $2 \text{ mW/cm}^2$  to  $200 \text{ mW/cm}^2$  and a treatment time from 10 minutes to 50 minutes (claim 64). Using a power density of  $2 \text{ mW/cm}^2$  ( $.002 \text{ W/cm}^2$ ) and a treatment time of 10 minutes (600 seconds), results in an energy flux of  $1.2 \text{ Joules/cm}^2$  ( $.002 \text{ W/cm}^2 * 600 \text{ seconds}$ ). Similarly, using a power density of  $20 \text{ mW/cm}^2$  ( $.02 \text{ W/cm}^2$ ) and a treatment time of 10 minutes (600 seconds), results in an energy flux of  $12 \text{ Joules/cm}^2$  ( $.02 \text{ W/cm}^2 * 600 \text{ seconds}$ ). Zharov discloses using diodes having a power of 0.5 to 5 Watts (Col. 4, 35-37). Zharov discloses using infrared radiation in addition to visible radiation in order to heat tissue (Col. 4, lines 35-41). Zharov discloses biological sensors to allow feedback and monitoring of the treatment (Col. 2, lines 44-51).

Claim 64 of Zharov, to which the Examiner refers, recites that "said radiation sources are adapted to uniformly grasp the zones of the patient's body responsible for immune system function and said wavelength of said radiation sources is selected from the red or infrared spectra at a flux of 2 to  $200 \text{ mW/cm}^2$  and a time exposure of 10 to 50 min. so as to alter the patient's immune activity through converting antibodies from the non-active into the active form." There is no indication in Zharov that the zones of the patient's body responsible for immune system function recited in claim 64 include the oral cavity. In fact, the phrase "immune system" appears only in claim 64 and at col. 4, line 66 to col. 5, line 4 in the following context: "The photomatrixes suggested are easy to put into human being's clothes, bed constant wear garment, subjects household activities (watches, spectacles, bracelets, etc.) to irradiate the body according to a special program so as to regulate his or her mood, to influence the biological rhythms, immune system, blood."

The passage at col. 4, line 35-37 of Zharov, to which the Examiner refers, recites that "[I]n addition, it is suggested to utilise high-power infrared diodes (up to 0.5-5 W) that provide the short-term heating of pathologic zones up to  $40-41^\circ\text{C}$  to enhance blood microcirculation, which is healthful at treating arthritis." Hence, Zharov discloses the use of such infrared diodes for treating arthritis and not irradiating the oral cavity. Further, even if one were to utilize diodes having a power of 0.5 to 5 Watts in Zharov's substrate 15 to irradiate oral cavity, one would not necessarily achieve the treatment of an area of facial skin by depositing a dose of radiation below that area. In

particular, there would be no guarantee that the radiation would have the appropriate characteristics (e.g., power density, energy density, and duration of exposure).

Hence, the use of Zharov's device, and particularly the substrate 15 shown in its FIGURE 2, to irradiate the oral cavity does not necessarily result in treating an area of the facial skin by depositing a dose of energy below that area. *See Crown Operations Intl Ltd v. Solutia Inc*, 62 U.S.P.Q.2d 1917 (Fed. Cir. 2002) ("Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient").

Thus, claim 1 is believed to be patentable over the cited art. Claims 5, 6, 9, 15-18, 19, 48, 49, and 57-73 depend, either directly or indirectly, on claim 1 and hence are also patentable over the cited art.

Claim 78, as amended, recites a biostimulation method, which comprises inserting at least a portion of a phototherapy applicator into an oral cavity; irradiating an area of tissue in the oral cavity with radiation from the phototherapy applicator, the radiation having *multiple distinct wavelength bands* corresponding to one or more absorption spectra of one or more light acceptors in the oral cavity or in tissue associated with the oral cavity, said one or more light acceptors absorbing at least one radiation wavelength in each of said bands; wherein at least *one of said wavelength bands causes increased microcirculation* in the soft tissues of the oral cavity and at least *another one of said wavelength bands causes a therapeutic effect*, and wherein the area of tissue is irradiated concurrently with said multiple wavelength bands so as to provide a desired biostimulation. Support for the amendment can be found, e.g., in dependent claim 87 (now incorporated in 78), as well as other portions of the specification.

Zharov does not teach or suggest concurrently irradiating the tissue in the oral cavity with multiple distinct wavelength bands, wherein at least one wavelength band causes increased microcirculation in the soft tissues of the oral cavity and at least another wavelength band causes a therapeutic effect. With regard to the use of different wavelengths, Zharov discloses that in non-malignant applications of photodynamic therapy, "photomatrixes with different wavelengths" can be used to irradiate "photosensitizer mixtures with different absorption bands" so as to kill different

kinds of bacteria. *See*, col. 4, lines 19-27. Whether or not such photomatrixes are employed to irradiate tissue with multiple wavelength bands *concurrently*, there is not indication in this passage, or any other portion of Zharov, that the oral cavity tissue is irradiated by multiple distinct wavelength bands to cause concurrently increased microcirculation and a therapeutic effect, as recited in amended claim 78. Such increased microcirculation can advantageously enhance the therapeutic effect.

Hence, claim 78 and claims 80-86, and 88-96, which depend either directly or indirectly on 78, are believed to be patentable over the cited art.

Claim 97 recites a method of treating a subject's blood, which comprises exposing at least a portion of a subject's oral cavity to radiation having wavelength components in a range of about 280 nm to about 1800 nm to irradiate blood flowing in vasculature of the oral cavity; irradiating the oral cavity with said radiation during separate treatment sessions such that a radiation power in a range of about 1 mW to about 10 W is administered to the oral cavity during each treatment session; and irradiating the subject's oral cavity for a sufficiently long time so as to expose substantially *an entire volume of the subject's blood* to said radiation in one or more treatment sessions.

Zharov does not teach or suggest irradiating a subject's oral cavity for a sufficiently long time so as to expose substantially *an entire volume* of the subject's blood to said radiation in one or more sessions. The Examiner states that "Zharov discloses multiple treatment sessions, specifically six procedures lasting 15 minutes each within one week (Col. 12, lines 8-10)." This passage of Zharov, however, relates to the use of multiple treatment sessions for irradiating a subject's elbow, and not a subject's blood via the oral cavity. Though Zharov teaches in other passages (e.g., col. 5, lines 19-20) that its device can be utilized for light therapy of blood, it does not teach that such a light therapy would include irradiating a subject's oral cavity for a sufficiently long time so as to expose substantially *an entire volume* of the subject's blood to radiation.

Hence, claim 97 as well as claims 23, 24, 26, 28-30, and 98-104, which depend on claim 97, are believed to be patentable over the cited art.

**Rejections Pursuant to 35 U.S.C. 103**

Claims 53-56 and 74-77 are rejected as being unpatentable over Zharov and further in view of U.S. 2003/0009158 of Perricone.

Claim 53 recites a method of biostimulation via an oral cavity, which comprises irradiating at least a portion of tissue in an oral cavity with electromagnetic radiation having a power density in a range of about  $1 \text{ W/cm}^2$  to about  $10 \text{ W/cm}^2$  and at least one wavelength corresponding to an absorption band of an endogenous photoreactive substance located in the portion of tissue, where the photoreactive substance absorbs sufficient electromagnetic radiation to cause the selected biostimulation effect.

Perricone discloses a method for treating aging or damaged skin by irradiating the affected skin areas with “an effective amount of blue and/or violet visible light having a wavelength of about 400 nm to about 500 nm.” *See*, Abstract.

Zharov does not teach irradiating the oral cavity with electromagnetic radiation having a power density in a range of about  $1 \text{ W/cm}^2$  to about  $10 \text{ W/cm}^2$ . In fact, the highest power density disclosed by Zharov is  $200 \text{ mW/cm}^2$ , which is significantly less than the  $1 \text{ W/cm}^2$  recited in claim 53. *See*, col. 4, lines 10-14 (“Modern semiconductor technology allows one to reach the flux from light diodes up to  $200 \text{ mW/cm}^2$  over the square up to  $1,000\text{-}2,000 \text{ cm}^2$  at the wavelength of absorption for widely known photosensitizers in the range of  $0.63$  to  $0.8 \mu\text{m}$ ”).

Although Perricone discloses that the light intensity may be varied from high to low with the high intensity generally referring to “an intensity above about  $800 \text{ mW/cm}^2$ ,” it does not teach or even suggest using such a high intensity light to irradiate the oral cavity.

Notwithstanding, the Examiner appears to argue that since Perricone discloses “a dermatological or cosmetic treatment of the mouth region (Par 0015 and abstract) using light having a power density of more than  $800 \text{ mW/cm}^2$  (Par 0019 and claim 3)” it would have been “obvious to a person having ordinary skill in the art at the time of applicant’s invention to use the power density disclosed by Perricone in the method taught by Zharov as it is an effective power density for dermatologically treating the mouth region of a patient.” *See*, Office Action, page 7. Perricone, however, teaches irradiating the mouth regions externally, and not through the oral cavity. In fact,

there is no indication in Perricone that its methods can be utilized for irradiating the oral cavity tissue.

Hence, independent claim 53 as well as claims 54-56 and 74-77, which depend either directly or indirectly on 53, are believed to be patentable over the cited art.

### **New Claims**

Independent claim new 105 recites a method of treating a subject's blood, which comprises exposing at least a portion of a subject's oral cavity to radiation having wavelength components in a range of about 280 nm to about 1800 nm and a power in a range of about 1 W to about 10 W to irradiate blood flowing in vasculature of the oral cavity, and irradiating the oral cavity for a sufficient duration to achieve at least one of kill one or more pathogens in the subject's blood, improve immunocompetence of blood macrophages, or destroy a metabolic blood component. New claim 106 depends on claim 105, and further recites that the one or more pathogens are any of bacteria and viruses. New claim 107 depends on claim 105 and further recites that the radiation has one or more wavelength components in a range of about 450 nm to about 460 nm. New claim 108 depends on claim 105, and further recites that the radiation has one or more wavelength components in a range of about 280 nm to about 400 nm. New claim 109 depends on claim 105, and further recites that the radiation has one or more wavelength components in a range of about 300 nm to about 320 nm. New claim 110 depends on claim 105 and further recites that the radiation has one or more wavelength components corresponding to absorption bands of Protoporphyrin IX. And new claim 111 depends on claim 105, and further recites that irradiating step results in deposition of an energy density dose in a range of about  $0.06 \text{ J/cm}^2$  to about  $30 \text{ J/cm}^2$  in said subject's blood. And new claim 112 depends on claim 105, and further recites that the metabolic component comprises bilirubin.

Support for new claims can be found, e.g., at Paragraphs [0146], [0148] and [0149] of the published patent application as well as original claims 20 – 29.

Applicants believe that these new claims distinguish patentably over the cited art. Although Zharov teaches that light can be employed to destroy bilirubin in blood, it does not teach or suggest



doing so by irradiating the oral cavity. On the contrary, Zharov discloses that its photomatrixes can be used "... to conduct *over-skin* blood therapy, treatment of yellow jaundice using light diodes of the blue range of spectrum to destroy bilirubin in blood." [Emphasis Added] col. 9, lines 24-27. For example, in FIGURE 12, Zharov shows a wrist band formed of several light emitting segments, where at least one section comprising 9-12 segments "can be used to conduct therapy of blood ..." col. 11, lines 59-60. Nor is there any reason to believe that the teachings of Zharov would inherently encompass the subject matter of the new claims. In particular, Zharov does not teach the radiation power recited in independent claim 105. Applicants note in this regard that Zharov teaches that light diodes having a power of 0.5 mW can be placed on a matrix surface used to irradiate the mouth for the treatment of inflammatory processes of the mouth. col. 12, lines 28-43. In contrast, claim 105 recites that radiation power is in a range of about 1 W to about 10 W.

## **CONCLUSION**

In view of the above amendments and remarks, Applicants respectfully request reconsideration and allowance of the application. Applicants invite the Examiner to call the undersigned if there are any remaining issues.

Dated: July 12, 2010

Respectfully submitted,

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